REMARKS

Reconsideration of this application and entry of this amendment is requested.

This application is a division of pending U.S. Application Serial No. 09/616,843. Additional pending related applications are U.S. Application Serial Nos. 10/025,567; 10/038,260; and PCT Application No. US/01/49588.

Claims 1, 3 and 17 have been amended to define applicants' method for reducing or eliminating the incidence of illnesses in humans caused by the presence of targeted colony-forming illness-causing immunogens from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*. This amendment overcomes the rejection of these claims under 35 U.S.C. 112 as containing subject matter which was not described in the specification. As noted by the examiner, the specification discloses a method of reducing or eliminating the incidence of food borne illness in humans caused by the presence of *E. coli, Listeria, Salmonella* and *Campylobacter* by inhibiting the ability of these colony-forming immunogens to adhere to the rumen or intestinal tracts of food animals thereby reducing the ability of the immunogens to multiply and colonize in the rumen or intestinal tracts of the food animals.

The IgY immunoglobulins binding to illness-causing immunogens is assisted by the IgM and IgA immunoglobulins. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attached themselves to their hosts. *Page 12, lines 11-13*. The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that the hen layers the unique IgY type immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Page 10, lines 4-5*. The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA

immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the binding of IgY immunogens to the illness-causing immunogens as more IgY immunogens are available to bind to the illness-causing immunogens. The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tracts of the animals. The IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen. The binding process is assisted by the IgY and IgA immunoglobulins by providing a longer sustaining effect of the antibody product. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulin thereby increasing its active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the intestinal tract of the animal thereby preventing multiplication and colonizing of the immunogen in the intestinal tract of the animal. Contamination of animal products and meat is eliminated due to the absence of the immunogen in the feed lot and its contents.

Applicants have discovered that egg IgY immunoglobulins must bind to protein-wasting immunogens to inhibit adherence of the immunogens in the intestinal tracts of animals. The totality of the teachings of the prior art do not reveal this discovery and advantageous results.

Applicants have conducted bead studies to demonstrate that antibodies disclosed in the

application bind to bacteria. Bead studies were used because they can be seen more clearly. The beads are activated and then coated with antibodies from specific egg products disclosed in the application. The following Exhibits are part of the bead studies.

Exhibit A are uncoated plastic beads.

Exhibit B shows egg-coated beads with no bacteria.

Exhibit C shows *E. coli* plus a bead with normal egg.

Exhibit D shows *E. coli* O157:H7 bound in three dimensions to an antibody coated bead.

The binding action of the egg immunoglobulins to applicants' claimed method for reducing or eliminating the incidence of illnesses in humans is a discovery beyond the teachings of the prior art.

The claims fall into three (3) groups. The separate groups of claims do not stand or fall together.

Group I comprises Claims 1, 2, 5, 8, 11 and 14. These claims define applicants' method for reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness-causing immunogens in meat. The illness-causing immunogens are from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*. The method includes drying of the entire contents of eggs having yolks with IgY immunoglobulins and albumin with IgM and IgA immunoglobulins. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals inhibit multiplication and colonization of the illness-causing immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the colony-forming illness-causing immunogens which inhibit the ability of the colony-forming illness-causing immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to

the illness-causing immunogens. The result is the colony-forming illness-causing immunogens cannot multiply or colonize in the intestinal tract of the animal thereby reducing or eliminating the incidence of illness in humans caused by the illness-causing immunogens.

Group II comprises Claims 3, 4, 6, 7, 9, 10, 12, 13, 15 and 16. These claims include the subject matter of parent Claims 5, 8, 11 and 14 and the process of drying the entire contents of the eggs having yolk IgY and albumin IgM and IgA immunoglobulins by coating dry feed carrier material with the entire contents of the eggs. The dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beat pulp. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds.

Group III comprises Claims 17, 18 and 19. These claims define a method for reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness-causing immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogens to adhere to the rumen or intestinal tracts of animals and reduce the ability of the immunogen to multiply. The immunogens include *E. coli, Listeria, Salmonella* and *Campylobacter*. The method includes providing a feed carrier material, coating the feed carrier material with the antibody yolk and albumin of the harvested eggs. The carrier material coated with the antibody yolk and albumin is distributed substantially uniform in animal feed. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals reduce or eliminate the incidence of illnesses in humans caused by the presence of colony-forming illness-causing immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the colony-forming illness-causing immunogens which inhibits the ability of the colony-forming illness-causing immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA

immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. The method does not include a separate step of drying the antibody yolk and albumin as required by the method of Claims 3, 4, 6, 7, 9, 10, 12, 13, 15 and 16.

Reconsideration of the rejection of the claims as unpatentable under 35 U.S.C. 103 is requested.

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

The Federal Circuit has also made it clear that the showing of a motivation to combine two or more references must be "clear and particular". See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated:

> When an obviousness determination is based on multiple references, there must be a showing of some "teaching, suggestion, or reason" to combine references. [Citation omitted].

> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be "clear and particular."

As the Federal Circuit also stated:

> "The factual inquiry whether to combine references must be thorough and searching" Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.

In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is submitted that the prior art of record does not contain a clear and particular motivation to combine these references.

The primary reference in all of the rejections based upon 35 U.S.C. 103(a) is U.S. Patent No. 5,080,895 (*Tokoro '895*)

Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdspersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro '895* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro '895* of an IgY immunoglobulin that binds to colony-forming illness-causing immunogens. The antibody containing substance also is used as a nutrition supplement, and as an additive to food animals. *Tokoro '895* does not provide a teaching of a method for reducing or eliminating the incidence of illnesses caused by colony-forming illness-causing immunogens by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to illness-causing immunogens, *E. coli, Listeria, Salmonella* and *Campylobacter*, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply and colonize.

Tokoro '895 does not coat a dry feed carrier with a mixed egg yolk and albumin product.

The object of the *Tokoro '895* disclosure is to administer to animals affected by an intestinal infection disease for therapeutic purposes. *Column 4, lines 1-4.* The *Tokoro '895* substance is also useful in the treatment of various infectious diseases, additives in food for livestock, cosmetics and medicines. *Column 4, lines 16-21.* Applicants' claimed method is not a treatment of a disease in animals. Applicants' method is the prevention of illnesses in humans by eliminating the illness-causing immunogens in animal meat. Applicants have discovered a new and useful method of preventing, as opposed to treating, illnesses in humans caused by colony-forming illness-causing immunogens.

The examiner has acknowledged that the teachings of *Tokoro '895* do not include "the method wherein the antibody in the eggs including IgY immunoglobulins in the yolks of the eggs whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted-colony forming illness-causing immunogen in the intestinal tract of the animals." *Office Action of July 28, 2004, page 7, lines 9-14.*

The separate and combined teachings of the second references, *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878, U.S. Patent No. 5,741,489, *Pell et al, Adesiyun et al* and U.S. Patent No. 4,166,867, do not suggest to one skilled in the art the binding of IgY immunoglobulins to illness-causing immunogens and that this binding is helped or assisted and increased by the IgY and IgA immunoglobulins. There is no clear and particular motivation for a person skilled in the art to combine these references. Further, any combination of these references would not produce applicants' claimed method for reducing or eliminating the incidence of illness in humans caused by the presence of targeted colony-forming illness-causing immunogens from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter.*

Respectfully submitted,

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